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KARL O. HESSE 13324 MAYES ROAD HUNTERSVILLE, NC 28078			EXAMINER CLOW, LORI A	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/629,448
Filing Date: July 29, 2003
Appellant(s): KELKAR ET AL.

Karl O. Hesse
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5 May 2008 appealing from the Office action mailed 16 May 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

WITHDRAWN REJECTIONS

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The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Rejections under 35 USC 112, 2nd paragraph in view of Applicant's arguments in the response filed 26 June 2007 (page 21, paragraph 5 to page 22, paragraph 5).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 10-16, and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The method and program product of the instant claims is directed to determining similarity between portions of gene expression profiles. The method comprises processing, listing, and providing an output of the listing. The instant method steps merely encompass data

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generated within a computer environment. The step of providing an output of the listing is not a recited physical method step. Further, no **specific** outcome is set forth in the claims such that the steps of the method produce a result that is immediately concrete, tangible, and useful. The output is not clearly defined as being a tangible output, for instance, to a user and therefore, the claim is non-statutory. The claims must, **as a whole**, satisfy section 101 and must be for practical application, which can be defined as:

1. The claimed invention “transforms” an article or physical object to a different state or thing.

[The claimed invention in the instant case does not transform any physical object or article.]

2. The claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors (see below) *[The claimed invention in the instant application does not produce a concrete, tangible, and useful result. There is no output to a **user**, for example, that results in a tangible result].*

Further, the program product of the instant claims does not provide that the execution of the code accomplishes a practical application (i.e. results in a *physical* transformation or produces a concrete, tangible, and useful *result*) and is therefore, non-statutory. The program product has program means for providing profile data and removing gene clusters. However, there are no further means that provide for the practical application of results in a concrete, tangible, and useful form, as in a means for output to a user.

(10) Response to Argument

A. Appellant’s argue, on page 27, beginning line 1, that the “specification and claims indeed do describe a method and a program product that produce a result that has substantial and

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credible utility as required by MPEP 2107 and that the claims are limited to a narrow practical application in a computer related art". Appellant goes on to argue that "the Examiner relies on the 'New Interim Guidelines' to interpret the requirements of the Federal Courts under the current law to require claiming 'output to a user'. Appellant believes that the Examiner is mistaken and is applying an interpretation of the definition of the word tangible that is:

- 1) narrower than appropriate under the current law and is
- 2) narrower than required under the 'New Guidelines'.

Appellant further asserts that "the Examiner appears to require separate interpretations of the words useful, concrete, and tangible. Applicants' attorney has found no basis in any of the Federal Circuit opinions using these words that imply that these terms are to have separate meanings".

This is not persuasive. Firstly, Appellant is arguing the instant rejection, in part, based on MPEP 2107, which pertains to compliance with the Utility requirement under 35 USC 101. However, the instant rejection is set forth under 35 USC 101 in regard to non-statutory subject matter, as discussed in MPEP 2106.

As set forth in MPEP 2106 regarding patent subject matter eligibility, the claimed invention **as a whole** must be useful and accomplish a practical application. That is, it must produce a "useful, concrete, **and** tangible result" (emphasis added) (*State Street Bank and Trust Co. v Signature Financial Group Inc.*, 149 F.3d 1368, 1373-74, 47 USPQ2d 1596, 1601-02 (Fe. Cir. 1998)). The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research

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(*Brenner v. Mason*, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96 (1966); *In re Fisher*, 421 F.2d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005); *In re Ziegler*, 992 F.2d 1197, 1200-03, 26 USPQ2d 1600, 1603-06 (Fed. Cir. 1993)).

To properly determine whether a claimed invention complies with the statutory requirement of invention, it is imperative to identify whether the claims fall within at least one of the four enumerated categories of patentable subject matter (i.e. process, machine, manufacture, or composition of matter). The analysis does not stop at this juncture, however, because claims directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible for patent protection, as they fall within a judicial exception. *Diehr*, 450 U.S. at 185, 209 USPQ at 7. Having established this fact, while abstract ideas, natural phenomena, and laws of nature are not eligible for protection, methods and products employing such to perform a real-world function may be. Again, the claim must be considered as a whole to determine whether it is for a particular application. Therefore, the claim is directed to a practical application of a 35 USC 101 judicial exception if it (a) transforms an article or physical object to a different state or thing; OR (b) it otherwise produces a useful, concrete, and tangible result.

In the instant case, the claims do not provide a physical transformation to a different state or thing and therefore, the claims are evaluated for providing a useful, concrete, **and** tangible result. To assess this matter, the focus is not on whether the steps taken to achieve a particular result are useful, concrete and tangible, but rather on whether the final result achieved by the claimed invention is useful, concrete, and tangible. As outlined in MPEP 2106, a "tangible result" is one in which sets forth a practical application of that judicial exception to produce a

real-world result. *Benson*, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because no "substantial practical application.").

Therefore, the MPEP provides ample guidance and decisions based on assessing the claims under 35 USC 101 regarding non-statutory subject matter. It is maintained that the instant process and program claims, 1-6, 10-16, and 20, containing abstract ideas, are not directed to a practical application of a judicial exception as they fail to provide a tangible result. The "output of the listing of clusters of gene expression" is not one that provides a real-world result, a result that is tangible. The "listing" could merely reside *in silico* and remain within the confines of a computer, for instance, and never be available for a real-world use or a tangible result.

For claims 10-16 in particular, directed to a "program product having computer readable code stored on a recordable media", further guidance in the MPEP is provided pertaining to computer-related non-statutory subject matter. Data structures and computer programs which impart functionality when employed as a computer component are considered "functional descriptive material". It is considered non-statutory when claimed as descriptive material *per se*, 33 F.3d at 1360, 31 USPQ2d at 1759. In the instant case, the program products stored on a recordable medium read on carrier wave storage (see specification at page 7, lines 14-15) and therefore, are not statutory (see recent decision in *In re Nuijten*; *CAFC 2006-1371*). Further, the program products consist of "means for" performing processes. The processes that are performed do not provide useful, concrete, and tangible results and therefore suffer from the same deficiencies as the method claims, explained above.

B. Appellant argues, beginning page 28, that "the Examiner's interpretation of the word tangible is unnecessarily narrow and that the 'Guidelines' at page 13 recite "Accordingly, a

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complete definition of the scope of 35 U.S.C. § 101, reflecting Congressional intent, is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent. The subject matter courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging."

This is not persuasive, for the reasons set forth above with regard to claim assessment and the fact that the instant claims are not directed to a practical application of a judicial exception as they fail to provide a tangible result.

Appellant contends that with regard to a "tangible result" the opposite meaning of "tangible" is "abstract" and that "the bare conversion of any binary data as in *Gottschalk v. Benson* or the bubble sort of any data as in *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759 [...] recites at page 14 of the "Guidelines" are examples of the abstract". Appellant further asserts that "Applicant's process does not convert or process just any data but is limited to useful, concrete and non-abstract gene expression profiles in a data base of such profiles" and that "Applicant's process is but one application of many possible applications of the mathematical steps involved in obtaining a useful result".

This is not persuasive, for the reasons set forth above which state that claims must provide a physical transformation to a different state or thing OR provide a useful, concrete, **and** tangible result. The instant claims fail the first test of providing a physical transformation and therefore are evaluated for whether or not they provide a useful, concrete, and tangible result. As

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stated above, the claims provide no such result, such that the result provided is tangible for a real-world use.

C. Applicant argues, on page 30, that “as evidenced by the references which applicants have attempted to incorporate by reference, but have acquiesced to the Examiners correct requirement to cancel, in addition to applicants teachings in the background art section of their specification, users in the medical profession find great value and usefulness in methods for finding similar gene expression profiles that are tangible and concrete. See for example US 6,406,853 abstract and claims 25, 26 and US Patent 6,436,642 column 26 beginning at line 15”.

This is not persuasive. Appellant is first reminded that each patent application is examined on its own merits and those merits of any other cases do not pertain. Secondly, for example, in US Patent 6,406,853, the claims comprise steps of physical transformation and cannot be likened to the claims of the instant application.

Rejections over claims 1-6, 10-16 and 20 under 35 USC 101 for non-statutory subject matter are hereby maintained.

Rejections pertaining to 35 USC 112, 2nd paragraph have been withdrawn, as stated above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

/Lori A. Clow, Ph.D./

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